Novel Low Concentration Meloxicam Tablets

FIELD OF THE INVENTION

The present invention is directed towards a novel oral application form comprising a divisible meloxicam tablet and its production method.

BACKGROUND OF THE INVENTION

Meloxicam (4-hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-2H-1,2-benzothiazine-3-carboxamide-1,1-dioxide) is a non-steroidal-antiinflammatoriy drug NSAID of the oxicam family. These types of drugs inhibit the enzyme prostaglandine H2 synthase, also called cyclooxygenase or COX. Meloxicam has antiinflammatoric, antipyretic and analgetic properties.

Meloxicam and its sodium and meglumine salts are described in EP0002482. The active ingredient alone has a low water solubility as shown in EP0945134 that also discloses the pH dependent solubility of meloxicam and its salts. There are many different application forms of meloxicam including a solution (EP1299107), a suspension (EP1066029), water-soluble granules (EP1558262), tablets made of either granules containing meloxicam (EP1942902) or of directly compressed powder mixtures (EP1385483 and GB2455875).

The objective of the present invention is to develop a readily accepted, chewable solid meloxicam tablet allowing precise administration of meloxicam even for exceptionally low concentrations.

BRIEF DESCRIPTION OF DRAWING

Figure 1A: Tablet shape and dimensions of 1 mg meloxicam chewable tablets.

Figure 1B: Tablet shape and dimensions of 2.5 mg meloxicam chewable tablets.

Figure 2: Tablet shape and breaking notch including dimensions.

DESCRIPTION OF THE INVENTION

Surprisingly, it has been found that such a readily accepted, chewable solid meloxicam tablet allowing precise administration of meloxicam even for exceptionally low concentrations can be prepared by the method of the current invention which is performed by direct compression of powders without any granulation step.

The tablet is administered to companion animals such as feline and canine, preferably canine with a body weight selected from the group consisting of 1kg to 70 kg, 1 kg to 60 kg, 1 kg to 50 kg, 1 kg to 40 kg, 1 kg to 30 kg, 1 kg to 20 kg, 1 kg to 10 kg. The tablet is administered to animals suffering from inflammation and pain in both acute and chronic musculoskeletal disorders in order to treat or alleviate such disorders. Other indications include locomoter disorders, lameness, respiratory diseases, pain such as postoperative pain, fever and inflammation.

The invention relates to a solid tablet that is directly-compressed of powder, comprising meloxicam or a pharmaceutically acceptable salt thereof and one or more excipients, characterised in that the tablets can be broken into two, three and/ or four units with each unit containing equal amounts of the active ingredient. A tablet is characterised in that meloxicam is homogenously dispersed within the tablet. In another embodiment the invention relates to a solid tablet that is directly-compressed of powder, comprising meloxicam or a pharmaceutically acceptable salt thereof and one or more excipients which are preferably homogenously dispersed within the tablet that can be broken into two, three and/ or four units, preferably two or four, more preferably two, with each

unit containing equal amounts of the active ingredient. The tablet contains excipients that are selected from the group consisting of fillers, disintegrants, pH adjusters, colourants, flow regulator, lubricants and flavour.

At least one of the excipient is a filler/ disintegrant selected from the group consisting of starch such as but not limiting to maize starch, microcristalline cellulose, calcium phosphate, lactose, maltodextrine, mannit, sorbit, cross-linked polyvinyl pyrrolidon and sodium carboxymethyl cellulose, preferably starch and microcristalline cellulose. When starch is the filler/ disintegrant, then its concentration is selected from the group consisting of 150 mg to 450 mg per tablet, preferably 150 to 300 mg, 160 to 290 mg, 170 to 280 mg, 170 to 270 mg, 180 to 260 mg, 170 to 250 mg, 190 to 240 mg, 200 to 240 mg, 210 to 240 mg, 220 to 240 mg and 230 to 240 mg per tablet, more preferably 235.0 mg per tablet, which are especially preferred in the tablet containing 1 mg meloxicam. Another preferred concentration is selected from the group consisting of 200 to 450 mg, 210 to 440 mg, 220 to 430 mg, 230 to 420 mg, 240 to 410 mg, 250 to 400 mg, 260 to 390 mg, 270 to 380 mg, 280 to 370 mg, 290 to 360 mg, 300 to 360 mg, 310 to 360 mg, 320 to 360 mg, 330 to 360 mg, 340 to 360 mg and 350 to 360 mg per tablet, preferably 351.5 mg per tablet, which are especially preferred in the tablet containing 2.5 mg meloxicam per tablet.

The second filler/ disintegrant has a concentration selected from the group consisting of 300 to 800 mg per tablet, preferably 300 to 600 mg, 300 to 500 mg, 400 to 500 mg per tablet, more preferred 400 mg per tablet, which are especially preferred in the tablet containing 1 mg meloxicam. Another preferred concentration is selected from the group consisting of 400 to 800 mg, 500 to 700 mg, 500 to 600 mg per tablet and 600 mg per tablet, which are especially preferred in the tablet containing 2.5 mg meloxicam per tablet.

Colouring agents that are used in the tablet include ferric oxide brown and/ or ferric oxide yellow, preferred are ferric oxide brown and ferric oxide yellow. The concentration of each colouring agent is in the range from 2 to 8 mg per tablet,

a preferred concentration is selected from the group consisting of 3 to 5 mg per tablet, 3 to 4 mg per tablet and 3.2 mg per tablet, which are especially preferred in the tablet containing 1 mg meloxicam. Another preferred concentration is selected from the group consisting of 3 to 8 mg per tablet, 4 to 6 mg per tablet, 3 to 5 mg per tablet and 4.8 mg per tablet, which are especially preferred in the tablet containing 2.5 mg meloxicam per tablet.

The tablet contains a pH adjuster selected from the group consisting of tartaric acid, maleic acid and sodium citrate dihydrate, preferably sodium citrate dihydrate. The concentration of a pH adjuster is in the range from 50 mg to 150 mg, preferred concentrations of the pH adjuster are selected from the group consisting of 50 to 100 mg, 50 to 90 mg, 50 to 80 mg, 50 to 70 mg, 60 to 90 mg, 60 to 80 mg and 60 to 70 mg per tablet, even more preferred 65.6 mg per tablet in the tablet containing 1 mg meloxicam. Another preferred concentration is selected from the group consisting of 75 to 150 mg, 85 to 140 mg, 85 to 130 mg, 85 to 120 mg, 85 to 110 mg, 85 to 100 mg, 90 to 150 mg, 90 to 140 mg, 90 to 130 mg, 90 to 120 mg, 90 to 110 mg, 90 to 100 mg per tablet and 98.4 mg per tablet, which are especially preferred in the tablet containing 2.5 mg meloxicam per tablet.

The tablet also contains a flow regulator selected from the group consisting of talc, anhydrous silicon dioxide and a lubricant, preferably anhydrous silicon dioxide. The concentration of a flow regulator is in the range from 2 to 8 mg, preferred concentrations the flow regulator are selected from the group consisting of 2 to 6 mg, 3 to 6 mg, 3 to 5 mg, 3 to 4 mg, 2 to 5 mg and 2 to 4 mg per tablet and even more preferred 4 mg, which are especially preferred in the tablet containing 1 mg meloxicam. Another preferred concentration is selected from the group consisting of 4 to 8 mg, 5 to 8 mg, 6 to 8 mg, 6 to 7 mg, 5 to 7 mg, 4 to 7 mg, 4 to 6 mg, 5 to 6 mg per tablet, and 6 mg per tablet, which are especially preferred in the tablet containing 2.5 mg meloxicam per tablet.

The tablet further contains lubricants selected from the group consisting of macrogols (= polyethylene glycols), stearic acid, aluminium stearate, calcium arachinat and magnesium stearate, preferably stearic acid, aluminium stearate, calcium arachinat and magnesium stearate, most preferred is magnesium stearate. The concentration of the lubricant is in the range from 5 to 15 mg per tablet, preferred concentrations of the lubricant are selected from the group consisting of 5 to 10 mg, 5 to 9 mg, 5 to 8 mg, 6 to 10 mg, 6 to 9, 6 to 8 mg, 7 to 10 mg, 7 to 9 mg, 7 to 8 mg per tablet and 8 mg per tablet, which are especially preferred in the tablet containing 1 mg meloxicam. Another preferred concentration of the lubricant is selected from the group consisting of 8 to 15 mg, 8 to 14 mg, 8 to 13 mg, 8 to 12 mg, 9 to 15 mg, 9 to 14 mg, 9 to 13 mg, 9 to 12 mg, 10 to 15 mg, 10 to 14 mg, 10 to 13 mg, 10 to 12 mg, 11 to 15 mg, 11 to 14 mg, 11 to 13 mg, 11 to 12 mg per tablet and 12 mg per tablet, which are especially preferred in the tablet containing 2.5 mg meloxicam per tablet.

The flavour is preferably an artificial beef flavour with a concentration range from 40 to 160 mg per tablet. Preferred concentrations of the flavour are selected from the group consisting of 40 to 100 mg, 50 to 100 mg, 60 to 100 mg, 70 to 100 mg, 80 to 100 mg per tablet and 80 mg per tablet which are especially preferred in the tablet containing 1 mg meloxicam. Another preferred concentration of the flavour is selected from the group consisting of 90 to 160 mg, 100 to 150 mg, 110 to 140 mg, 110 to 130 mg per tablet and 120 mg per tablet, which are especially preferred in the tablet containing 2.5 mg meloxicam per tablet.

According to the invention, the tablet contains 0.5 to 5 mg of meloxicam and has a tablet weight of 500 mg to 2000 mg. Preferably the tablet contains 0.5 mg to 5 mg of meloxicam and has a total tablet weight of 500 mg to 2000 mg with a tablet diameter ranging from 10 mm to 20 mm. Additionally the tablet has preferably a height ranging from 3 mm to 8 mm, more preferred 4 mm to 8 mm, 5.3 mm to 7.3 mm or 4.5 mm to 6.5 mm, even more preferred 5 mm, 5.5 mm or 6.3 mm. The preferred amount of meloxicam per tablet is from 1 mg to 4 mg,

more preferred from 1 mg to 3 mg or 1.5 mg to 2.5, even more preferred is 1 mg and 2.5 mg. The tablet has a total weight in the range from 500 to 2000 mg, preferably from 700 to 1500 mg, most preferred 800 mg and 1200 mg. In a preferred embodiment the tablet containing 0.5 mg to 1.8 mg meloxicam has a total weight of about 500 mg to 900 mg and a diameter ranging from 10 to 15 mm. Even more preferred is a tablet containing 0.5 mg to 1.8 mg meloxicam with a total weight of about 500 mg to 900 mg, a diameter ranging from 10 mm to 15 mm and a height ranging from 4.5 mm to 6.5 mm. In another preferred embodiment the tablet containing 1.9 to 5 mg meloxicam has a total weight of 900 to 2000 mg and a diameter of 15 mm to 20 mm. Even more preferred is a tablet containing 1.9 to 5 mg meloxicam with a total height of 900 mg to 2000 mg, a diameter of 15 mm to 20 mm and a thickness ranging from 5.3 mm to 7.3 mm. In an especially preferred embodiment of the invention the tablet contains 1 mg meloxicam homogenously dispersed in a total tablet weight of 800 mg and/ or 2.5 mg meloxicam in a tablet with a total weight of 1200 mg. The flavour contributes 2 to 15% of the total weight of the tablet. According to the invention the tablet most preferably contains 1 mg meloxicam per 800 mg tablet and the flavour content is 10% by weight per tablet or the tablet contains 2.5 mg meloxicam per tablet with a total weight of 1200 mg with a flavour content of 10% by weight per tablet. Preferably, the flavour according to the invention is an artificial beef flavour.

According to another aspect the tablet has a shape as exemplary shown in figure 1A and 1B as well as figure 2. Generally, the tablet contains 0.5 mg to 5 mg of meloxicam and has a total tablet weight of 500 mg to 2000 mg. The dimensions of the tablet are given by its diameter, which ranges from 10 mm to 20 mm, and its height ranging from 3 mm to 8 mm. Preferably the tablet containing 1 mg meloxicam has a total weight of 500 mg to 900 mg, a diameter ranging from 10 mm to 20 mm, 11 mm to 18 mm, 12 mm to 17 mm, 13 mm to 16 mm, 14 mm to 15 mm, an alternative preferred range is from 12 mm to 15mm; and a height ranging from 4 mm to 8 mm, 5 mm to 7 mm, 5 mm to 6 mm, preferably 5 mm to 6 mm. Especially preferred is a tablet, as exemplary shown

in figure 1A, that contains meloxicam in a concentration of 1.0 mg per tablet with a total weight of 800 mg, a diameter of 14 mm and a height of 5.5 mm. Preferably the tablet containing 2.5 mg meloxicam has a total weight of 900 to 2000 mg, a diameter ranging from 10 mm to 20 mm, 11 mm to 18 mm, 12 mm to 17 mm, 13 mm to 16 mm, 14 mm to 15 mm, an alternative preferred range is from 15 mm to 18 mm or 15 mm to 17 mm; and a height ranging from 4 mm to 8 mm, 5 mm to 7 mm, 5 mm to 6 mm, an alternative preferred range is from 5 mm to 8 mm. Especially preferred is a tablet, as exemplary shown in figure 1B, containing meloxicam in a concentration of 2.5 mg per tablet with a total weight of 1200 mg, a diameter of 16 mm and a height of 6.3 mm.

As shown in figure 1A and 1B the tablet has a breaking notch/ score line that enables the tablet to be broken into two units resulting in two units containing an equal amount of meloxicam due to its homogenous distribution within the tablet.

According to another aspect the tablet has two breaking notches/ score lines that are perpendicular to one another as exemplary shown in figure 2. Thus, the tablet can be quartered resulting into either four or two units of equal amount of meloxicam, which is only possible because of the homogenous distribution of meloxicam in the tablet.

The solid formulation according to the invention is a directly compressed tablet without any granulation step. The active ingredient in the solid formulation is preferably meloxicam as a free base.

In contrast to the state of the art the tablet according to the invention is produced by compressing a powder directly into a tablet resulting in a low content of the active ingredient meloxicam. Additionally, the tablet has a large size which was desire as it makes it easier for the animal to pick up the tablet. Additionally, the size was also important to make it easier to divide the tablet in order to achieve a precise administration of the drug in case of a low dose application. For example, as described above the tablet containing 1 mg of

meloxicam has a diameter of 14 mm, whilst the tablet containing 2.5 mg meloxicam has a diameter of 16 mm. As previously described, the concentration of the active pharmaceutical ingredient is low and considered to be in a critical phase, which implicates that the concentration of meloxicam is in a concentration range that makes it difficult to produce a large tablet with a uniform distribution of the active ingredient within tablet.

Surprisingly, it has been found that the production method of this invention enables a uniform distribution of meloxicam despite the low concentration of the active ingredient. This enables the production of a tablet that can be divided as described with an ensured precise administration. As described above, the final tablet is preferably marked with a breaking notch/ score line that enables the user to break the tablet more easily into two, three and/ or four pieces. The direct compression process comprises the following steps:

1) Premixing of meloxicam with 10 – 50% of a filler/ disintegrant, preferably 20 to 40%, more preferred 25 – 35%, even more preferred is 33% followed by screening through suitable a mesh that has a mesh size of 0.6 to 1.5 mm, preferably 0.7 to 1.4 mm, more preferred 0.8 to 1.3 mm, even more preferred is a mesh size selected from the group consisting of 0.6 mm, 0.8 mm, 1.0 mm and 1.5 mm.

2) Premixing of a pH adjuster and one or more colouring agents followed by screening through a suitable mesh that has a mesh size of 0.6 to 1.5 mm, preferably 0.7 to 1.4 mm, more preferred 0.8 to 1.3 mm, even more preferred is a mesh size selected from the group consisting of 0.6 mm, 0.8 mm, 1.0 mm and 1.5 mm.

3) Mixing of 90-50% of a filler/ disintegrant, preferably 60 to 80%, more preferred 60 – 70%, even more preferred is 67%, a second filler/disintegrant, flow regulator, lubricant and artificial flavour followed by screening through a suitable mesh that has a mesh size of 0.6 to 1.5 mm, preferably 0.7 to 1.4 mm,

more preferred 0.8 to 1.3 mm, even more preferred is a mesh size selected from the group consisting of 0.6 mm, 0.8 mm, 1.0 mm and 1.5 mm.

4) Admixing the blends obtained in steps 1) and 2) followed by screening through a suitable mesh that has a mesh size of 0.6 to 1.5 mm, preferably 0.7 to 1.4 mm, more preferred 0.8 to 1.3 mm, even more preferred is a mesh size selected from the group consisting of 0.6 mm, 0.8 mm, 1.0 mm and 1.5 mm.

5) Final blending of the mixtures obtained in steps 3) and 4) followed by screening through a suitable mesh that has a mesh size of 0.6 to 1.5 mm, preferably 0.7 to 1.4 mm, more preferred 0.8 to 1.3 mm, even more preferred is a mesh size selected from the group consisting of 0.6 mm, 0.8 mm, 1.mm and 1.5 mm.

6) Compression of the powder mixture obtained in step 5) into a tablet.

The direct compression process comprises preferably the following steps:

1) Premixing of meloxicam with 10 – 50% of maize starch, preferably 20 to 40%, more preferred 25 – 35%, even more preferred is 33% of maize starch followed by screening through a suitable mesh that has a mesh size of 0.6 to 1.5 mm, preferably 0.7 to 1.4 mm, more preferred 0.8 to 1.3 mm, even more preferred is a mesh size selected from the group consisting of 0.6 mm, 0.8 mm, 1.0 mm and 1.5 mm.

2) Premixing of sodium citrate dihydrate, ferric oxide brown and ferric oxide yellow followed by screening through a suitable mesh that has a mesh size of 0.6 to 1.5 mm, preferably 0.7 to 1.4 mm, more preferred 0.8 to 1.3 mm, even more preferred is a mesh size selected from the group consisting of 0.6 mm, 0.8 mm, 1.0 mm and 1.5 mm.

3) Mixing of 90-50% of the maize starch, preferably 60 to 80%, more preferred 60 – 70%, even more preferred is 67% of maize starch, microcrystalline cellulose, anhydrous silicon dioxide, magnesium stearate and artificial beef flavour followed by screening through a suitable mesh that has a mesh size of 0.6 to 1.5 mm, preferably 0.7 to 1.4 mm, more preferred 0.8 to 1.3 mm, even more preferred is a mesh size selected from the group consisting of 0.6 mm, 0.8 mm, 1.0 mm and 1.5 mm.

4) Admixing the blends obtained in steps 1) and 2) followed by screening through a suitable mesh that has a mesh size of 0.6 to 1.5 mm, preferably 0.7 to 1.4 mm, more preferred 0.8 to 1.3 mm, even more preferred is a mesh size selected from the group consisting of 0.6 mm, 0.8 mm, 1.0 mm and 1.5 mm.

5) Final blending of the mixture obtained in steps 3) and 4) followed by screening through a suitable mesh that has a mesh size of 0.6 to 1.5 mm, preferably 0.7 to 1.4 mm, more preferred 0.8 to 1.3 mm, even more preferred is a mesh size selected from the group consisting of 0.6 mm, 0.8 mm, 1.0 mm and 1.5 mm.

6) Compression of the powder mixture obtained in 5) into a tablet.

Thus according to a further aspect, a solid tablet comprising meloxicam or a pharmaceutically acceptable salt thereof is provided, wherein said solid tablet is obtainable by the direct compression process of a powder mixture comprising the steps 1 to 6 as described above.

According to a further aspect, a solid tablet comprising meloxicam or a pharmaceutically acceptable salt thereof as described herein is provided, wherein the production of said solid tablet comprises on or more of the process steps 1 to 6 as described above. For instance, said production process comprises step 1, steps 1 + 4, steps 1 + 4 + 6 or step 1 + 4 + 5 + 6.

According to a further aspect a method of producing a solid tablet is provided, wherein such method preferably consists of steps 1 to 6 as described above.

Method of Production

The following description of the production method has to be regarded as a further example and thus not to be understood as limiting:

The first step in the manufacturing process is the premixing of the active ingredient such as meloxicam or a pharmaceutically active salt thereof with a portion of starch followed by screening. Due to the low total amount of meloxicam or the pharmaceutically acceptable salt thereof in the tablet mixture, subsequent mixing with for example about 900 revolutions is necessary after addition of another screened mixture containing sodium citrate and the ferric oxides to ensure a homogeneous distribution of the active ingredient in the matrix. Finally, a mixture of screened microcrystalline cellulose, meat flavour, the remaining amount of starch, colloidal silica anhydrous and magnesium stearate is added, followed by a final blending with for example about 350 revolutions of the mixing container.
The final blend is directly compressed into tablets.

Examples

I. Composition for a tablet with a total weight of 800 mg comprising 1 mg meloxicam and 10 % flavour.

Ingredients	mg/ tablet
Meloxicam	1.0
Sodium Citrate Dihydrate	65.6
Maize Starch	235.0
Ferric Oxide Brown	3.2
Ferric Oxide Yellow	3.2

Microcrystalline Cellulose	400.0
Artificial Powdered Beef Flavour	80.0
Anhydrous Silicon Dioxide	4.0
Magnesium Stearate	8.0
Total	800.0

II. Composition for a tablet with a total weight of 1200 mg comprising 2.5 mg meloxicam and 10 % flavour.

Ingredients	mg/ tablet
Meloxicam	2.5
Sodium Citrate Dihydrate	98.4
Maize Starch	351.5
Ferric Oxide Brown	4.8
Ferric Oxide Yellow	4.8
Microcrystalline Cellulose	600.0
Artificial Powdered Beef Flavour	120.0
Anhydrous Silicon Dioxide	6.0
Magnesium Stearate	12.0
Total	1200.0

Claims

1. A solid tablet that is directly-compressed of powder, comprising meloxicam or a pharmaceutically acceptable salt thereof and one or more excipients, characterised in that the tablets can be broken into two, three and/ or four units with each unit containing equal amounts of the active ingredient.

2. A tablet according to claim 1, characterised in that meloxicam is homogenously dispersed within the tablet.

3. A tablet according to claim 1 or 2, characterised in that the excipients are selected from the group consisting of fillers, disintegrants, pH adjusters, colourants, flow regulator, lubricants and flavour.

4. A tablet according to claim 1 to 3, characterised in that at least one of the excipients is a filler/ disintegrant selected from the group consisting of calcium phosphate, lactose, maltodextrine, mannit, sorbit, cross-linked polyvinyl pyrrolidon, sodium carboxymethyl cellulose, starch and microcristalline cellulose.

5. A tablet according to one of claims 1 to 4, characterised in that the colourants are ferric oxide brown and/ or ferric oxide yellow.

6. A tablet according to one of claims 1 to 5, characterised in that the pH adjuster is selected from the group consisting of tartaric acid, maleic acid and sodium citrate dihydrate.

7. A tablet according to one of claims 1 to 6, characterised in that the flow regulator is selected from the group consisting of talc, anhydrous silicon dioxide and a lubricant.

8. A tablet according to one of claims 1 to 7, characterised in that the lubricant is selected from the group consisting of macrogols (= polyethylene glycols), stearic acid, aluminium stearate, calcium arachinate and magnesium stearate.

9. A tablet according to one of claims 1 to 8, comprising 0.5 to 5 mg of meloxicam and a tablet weight of 500 mg to 2000mg.

10. A tablet according to one of claims 1 to 9, comprising a flavour in an amount of 2 to 15% by weight of the total tablet weight.

11. A tablet according to one of claims 1 to 10, characterised in that the flavour is an artificial beef flavour.

12. A tablet according to one of claims 1 to 11, characterised in that the solid formulation contains meloxicam as a free base.

13. A direct compression process, comprising the following steps:
1) Premixing of meloxicam with 10 – 50% of a filler/ disintegrant followed by screening through suitable a mesh.
2) Premixing of a pH adjuster and one or more colouring agents followed by screening through a suitable mesh.
3) Mixing of 90-50% of a filler/ disintegrant, a second filler/disintegrant, flow regulator, lubricant and artificial flavour followed by screening through a suitable mesh
4) Admixing the blends obtained in steps 1) and 2) followed by screening through a suitable mesh.
5) Final blending of the mixtures obtained in steps 3) and 4) followed by screening through a suitable mesh
6) Compression of the powder mixture obtained in step 5) into a tablet.

14. A direct compression process according to claim 13, wherein the steps comprise:

1) Premixing of meloxicam with 33% of a filler/ disintegrant followed by screening through a suitable mesh.

2) Premixing of a pH adjuster and one or more colouring agent followed by screening through a suitable mesh.

3) Mixing of 67% of a filler/ disintegrant, a second filler/disintegrant, flow regulator, lubricant and an artificial flavour followed by screening through a suitable mesh.

4) Admixing the blends obtained in steps 1) and 2) followed by screening through a suitable mesh.

5) Final blending of the mixture obtained in steps 3) and 4) followed by screening through a suitable mesh.

6) Compression of the powder mixture obtained in step 5) into a tablet.

15. A solid tablet comprising meloxicam or a pharmaceutically acceptable salt thereof, wherein the solid tablet is obtainable by the direct compression process according to claim 13 or 14.