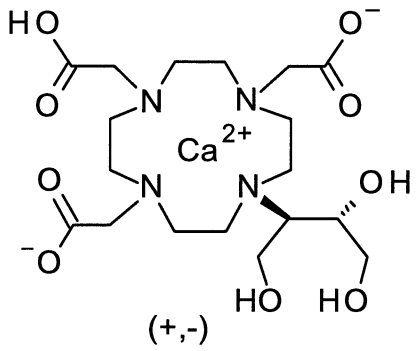
Patent Claims

1. Compound of the formula (I) in crystalline form of the modification A



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(I),

characterized in that the x-ray powder diffraction diagram of the compound shows peak maxima of the 2 theta angle at 7.6°, 9.1°, 11.1°, 11.3°, 11.9° and 12.3°.

2. Compound of the formula (I) according to claim 1, characterized in that it is a monohydrate with 2.0 – 2.5 weight % ethanol.

3. Method for the production of the compound of the formula (I) according to Claim 1 or 2, characterized in that the gadolinium complex of dihydroxy-hydroxy-methylpropyl-tetraazacyclododecane-triacetic acid (gadobutrol) is decomplexed, the precipitated gadolinium salt is removed, then the solution with the free ligands is bound to an acidic ion exchanger, then eluted with aqueous basic solution, then complexed with calcium^{2+} ions, then the Ca:butrol stoichiometry is adjusted to 1:1, the crystallization is then performed from aqueous ethanol with a water content of 9 - 11 weight % water and then the product is dried and thus the compound of the formula (I) according to Claim 1 or 2 is isolated.

4. Method for the production of the compound of the formula (I) according to Claim 1 or 2, characterized in that the gadolinium complex of dihydroxy-hydroxy-methylpropyl-tetraazacyclododecane-triacetic acid (gadobutrol) is decomplexed with oxalic acid in water with heating, the precipitated gadolinium oxalate is filtered off, then the free ligand is bound on an acidic ion exchanger, then eluted with aqueous ammonia solution, and is complexed with calcium^{2+} ions after concentration of the solution, then the Ca:butrol stoichiometry is adjusted to 1:1, then it is heated under reflux from aqueous ethanol with a water content of 9 - 11 weight % water, then cooled, after isolation it is dried, and thus the compound of the formula (I) according to Claim 1 or 2 is isolated.

5. Method for the production of the compound of the formula (I) according to Claim 3 or 4, characterized in that calcium carbonate is used for the complexation.

6. Method for the production of the compound of the formula (I) according to Claim 3, 4 or 5, characterized in that calcium carbonate is used for the complexation and that the complexation is performed in a temperature range of ≥20°C and ≤25°C.

7. Compound of the formula (I) according to Claim 1 or 2, produced by one of the methods according to one of Claims 3, 4, 5 or 6.

8. Compound of the formula (I) according to Claim 1 or 2 in a purity of ≥99.0%.

9. Compound of the formula (I) according to Claim 1 or 2 in a purity of ≥99.7%.

10. Use of a compound of the formula (I) according to one of Claims 1, 2, 7, 8 or 9 for the production of galenical formulations of gadobutrol.