LINE PRIVATIONAL APPLICATION NO:     CONCERNING A FILING UNDER SUSC 37     US. APPL O ("O'O'O'O'O'O'O'O'O'O'O'O'O'O'O'O'O'O'O'	FORM PTO-13%	U.S. DEPARTMENT OF COMMERCE PATENT A TRANSMITTAL LETTER TO THE U	ND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER: 9623 V/vmf/as							
INTERNITOMAL APPLICATION NO::         INTERNATIONAL FILMC DATE:         PRORTY DATE CLUMED: 14 JUNE 1998 (14.06.39)           CT/FEPOD05358         THEE OF INVENTION: CONTROLLED RELEASE AND TASTE MSKING ORAL PHARMACEUTICAL COMPOSITIONS           APPLICANT(S) FOR DOJEO/US:         Robert OVILLA, Massimo PEDRANI, Mauro ALANI and Lorenzo FOSSATI           Applicant herewith submits to the United States Designated/Bedid Office (00/EO/US) the following items and other information:         .           1.         X         This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.         .           2.         This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.         .           3.         X         This sepress request to begin national assemination procedures (55 U.S.C. 371(c)) and pCT Articles 22 and 39(1).         .           4.         A proper Demand for International Prefiminary Examination was made by the 19th month from the earliest claimed priority date.         .           5.         X         A copy of the International Application as filed (35 U.S.C. 371(c)(2)).         .           4.         A copy of the International Application was filed in the United States Receiving Office (RO/US).         .           6.         Is transmitted by the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).         .           1.         A translation of the international Application under PCT Article 19 (35 U.S.C. 371(c)(3)).         .		CONCERNING A FILING UNDER	R 35 U.S.C. 371	U.S. APPT. NO (11 more). See 370551.53 2							
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U.S. APPLICATION NO	<u><u></u><u></u></u>	ATTORNEY'S DOCKET NO. 9623 V/vmf/as							
1	•	CALCULATIONS PTO USE ONLY							
17 X The fo	llowing fees are submitted:								
BASIC NATIONAL F Neither international (37 CFR1.445(a)(2)) the EPO or JPO	EE (37 CFR 1.492(a)(1)-(5)): preliminary examination fee (37 ( paid to USPTO and International								
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		ENTER APPROPRIATE E	BASIC FEE AMOUNT =	\$	890.00				
Surcharge of \$130.00 prietity date (37 CFR	) for furnishing the oath or declar 1.492(e)).	ation later than months from t	he earliest claimed	\$					
	NUMBER FILED	NUMBER EXTRA	RATE	\$					
Total claims	14 - 20 =	0	X \$18.00	\$					
Independent claims	1 - 3 =	0	X \$84.00	\$					
	ENT CLAIMS(S) (if applicable)		+ \$280.00	\$					
nu .	-	TOTAL OF ABO	VE CALCULATIONS =	\$	890.00				
Reduction of ½ for fili 1.22 ₅	ng by small entity, if applicable.	Applicant claims Small Entity	Status under 37 CFR	\$	445.00				
	1		SUBTOTAL =	\$	445.00				
Processing fee of \$13 priority date (37 CFR	30 for furnishing the English trans 1.492(f)).	\$							
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Fee for recording the appropriate cover she	enclosed assignment (37 CFR1 eet (37 CFR 3.28, 3.31). \$40.00	.21(h)). The assignment must per property	be accompanied by an +	\$	40.00				
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a. X A cheo	k in the amount of \$ <u>485.00</u> to c	over the above fees is enclose	ed.						
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c. X The Commissioner is hereby authorized to charge any additional fees which may be required by 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. <b>25-0120</b> . A duplicate copy of this sheet is enclosed.									
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## CONTROLLED RELEASE AND TASTE MASKING ORAL PHARMACEUTICAL

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PCT/EP00/05356

The present invention relates to controlled release and taste-masking compositions containing one or more active principles incorporated in a three-component matrix structure, i.e. a structure formed by successive amphiphilic, lipophilic or inert matrices and finally incorporated or dispersed in hydrophilic matrices. The use systems for the control of the plurality of of a ingredient active modulates dissolution of the the dissolution rate of the active ingredient in aqueous and/or biological fluids, thereby controlling the release kinetics in the gastrointestinal tract, and it also allows the oral administration of active principles having unfavourable taste characteristics or irritating action on the mucosae of the administration site, particularly in the buccal area.

The compositions of the invention can contain active principles belonging to the therapeutical classes of analgesics, antiinflammatories, cardioactives, tranquillizers, antihypertensives, disinfectants and topical antimicrobials, antiparkinson drugs, antihistamines and are suitable to the oral administration or for act<u>ing</u> topically at some areas of the gastrointestinal tract.

#### TECHNOLOGICAL BACKGROUND

The preparation of a sustained, controlled, delayed or 25 anyhow modified release form can be carried out according to different known techniques:

 The use of inert matrices, in which the main component of the matrix structure opposes some resistance to the penetration of the solvent due to the poor affinity towards aqueous fluids; such property being known as lipophilia.

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WO 00/76478

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- 2. The use of hydrophilic matrices, in which the main component of the matrix structure opposes high resistance to the progress of the solvent, in that the presence of strongly hydrophilic groups in its chains, mainly branched, remarkably increases viscosity inside the hydrated layer.
- The use of bioerodible matrices, which are capable of being degraded by the enzymes of some biological compartment.

10 All the procedures listed above suffer, however, from drawbacks and imperfections.

<u>Inert matrices</u>, for example, generally entail nonlinear, but esponential, release of the active ingredient.

<u>Hydrophilic matrices</u> have a linear behaviour until a certain fraction of active ingredient has been released, then they significantly deviate from linear release.

Bioerodible matrices are ideal to carry out the socalled "site-release", but they involve the problem of finding the suitable enzyme or reactive to degradation. Furthermore, they frequently release in situ metabolites that are not wholly toxicologically inert.

A number of formulations based on inert lipophilic matrices have been described: Drug Dev. Ind. Pharm. 13 (6), 1001-1022, (1987) discloses a process making use of varying amounts of colloidal silica as a porization element for a lipophilic inert matrix in which the active ingredient is incorporated.

The same notion of canalization of an inert matrix is described in US 4,608,248 in which a small amount of a hydrophilic polymer is mixed with the substances forming an inert matrix, in a non sequential compenetration of different matrix materials.

EP 375,063 discloses a technique for the preparation of multiparticulate granules for the controlled-release of

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the active ingredient which comprises co-dissolution of polymers or suitable substances to form a inert matrix with the active ingredient and the subsequent deposition of said solution on an inert carrier which acts as the core of the 5 device. Alternatively, the inert carrier is kneaded with the solution containing the inert polymer and the active ingredient, then the organic solvent used for the their dissolution is evaporated off to obtain a solid residue. The resulting structure is a "reservoir", i.e. is not macroscopically homogeneous along all the symmetry axis of the final form.

The same "reservoir" structure is also described in Chem. Pharm. Bull. 46 (3), 531-533,, (1998) which improves the application through an annealing technique of the inert polymer layer which is deposited on the surface of the pellets.

To the "reservoir" structure also belong the products the technique described in obtained according to WO 93/00889 which discloses a process for the preparation of pellets in hydrophilic matrix which comprises:

- dissolution of the active ingredient with gastroresistant hydrophilic polymers in organic solvents;
- drying of said suspension;
- subsequent kneading and formulation of the pellets in a hydrophilic or lipophilic matrix without distinction of effectiveness between the two types of application.

ΕP discloses a multiparticulate with 0 453 001 "reservoir" structure inserted in a hydrophilic matrix. The basic multiparticulate utilizes two coating membranes to decrease the release rate of the active ingredient, a pHdependent membrane with the purpose of gastric protection and a pH-independent methacrylic membrane with the purpose of slowing down the penetration of the aqueous fluid.

WO 95/16451 discloses a composition only formed by a

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