

Validation Form for a New Line-extension to a Marketing Authorisation

Product Name:	OK ?	
Company:		
SP Number:	Route of Administration:	
Administrative particulars:	Application Form:	

Target species:			
Sex:	Age:	Weight:	Food Role:

Therapeutic Group:

MRL Status of Ingredient(s):

Product Formula	
Active(s):	Excipient(s):

Part I	Comments:
Summary:	
SPC (I.B)	Page(s): -
Label (I.B)	Page(s): -
Package Insert (I.B)	Page(s): -
TSE declaration	Page(s): -
Manufacturer's Licence	Page(s): -
Quality Expert Report: <i>Critique</i> (I.C)	Page(s): -
Expert CV (I.C) ^[h1]	Page(s): -
Summary tables (I.C)	Page(s): -
Safety Expert Report: <i>Critique</i> (I.C)	Page(s): -
Residues Expert Report: <i>Critique</i> (I.C)	Page(s): -
Ecotox Expert Report: <i>Critique</i> (I.C)	Page(s): -
Expert CV(s) (I.C) ^[h2]	Page(s): -
Summary tables (I.C)	Page(s): -
Efficacy Expert Report: <i>Critique</i> (I.C)	Page(s): -
Expert CV (I.C) ^[h3]	Page(s): -
Summary tables (I.C)	Page(s): -

Part II Quality:	Comments:
Product Composition data (II.A) [h4]	Page(s): -
Active, Is it New to UK VMP's ?[h5]	
Product - Method of Manufacture (II.B)	Page(s): -
New Source of Active (II.C) [h6]	
Chemistry of Active in Dossier ? (II.C)	Page(s): -
Certificate of Suitability ?	Page(s): -
EDMF - Applicants part Enclosed (II.C)	Page(s): -
- Letter of Authorisation	Page(s): -
- Complete EDMF from AIM	Page(s): -
Excipients, New to UK VMP's?[h7]	
Specifications - Active (II.C)	Page(s): -
- Excipient (II.C)	Page(s): -
- Finished Product (II.E)	Page(s): -
Stability Data Minimum of 3 Batches with 6 Months data for NCE or 2 batches with 6 Months data for non NCE. (II.F) [h8]	Page(s): -

Part III Safety:	Comments:
Precise ID and Formulation (III.A.1) [h9]	Page(s): -
Pharmacodynamics (III.A.2) [h10]	Page(s): -
Pharmacokinetics (III.A.2) [h11]	Page(s): -
Single dose Toxicity (III.A.3) [h12]	Page(s): -
Repeated Dose Toxicity (III.A.3) [h13]	Page(s): -
Reprotox and teratogenicity (III.A.3) [h14]	Page(s): -
Mutagenicity (III.A.3)	Page(s): -
Carcinogenicity (III.A.3)	Page(s): -
Other Tests (neurotox antimicrobial effects & immunotoxicity) (III.A.4)	Page(s): -
Operator Safety (III.A.6)	Page(s): -
Ecotox:	Comments
Phase I ERA provided ? (III.A.5)	Page(s): -
Phase II ERA Incl supp. data ? (III.A.5)	Page(s): -
70/524 Feed Additives Application	

Residue data for Food producing species only	
Pharmacokinetics (III.B.2.1)	Page(s): -
Residue depletion studies (III.B.2.2)	Page(s): -
Proposed MRL (III.B.2.3)	Page(s): -
Proposed Withdrawal period(s) (III.B.2.4)	Page(s): -
Analytical Method (III.B.3.1)	Page(s): -
Validation of analytical method (III.B.3.2)	Page(s): -

Part IV	Comments:
Efficacy:	
Pharmacodynamics (IV.1.A)	Page(s): -
Pharmacokinetics (IV.1.A)	Page(s): -
Target species tolerance (including SARS if appropriate) (IV.1.B)	Page(s): -
Resistance (IV.1.C)	Page(s): -
Field Trials	Page(s): -
Laboratory Studies	Page(s): -
Published Literature	Page(s): -
Previous ATC, ATX plus details ?	Page(s): -

Page: 1

[h1]Must be signed and dated by expert

Page: 1

[h2]Must be signed and dated by expert

Page: 1

[h3]Must be signed and dated by expert

Page: 2

[h4]Qualitative and Qualitative showing all ingrediants, quantities and grades

Page: 2

[h5]Check MA Memo's to find out whether or not the ACTIVE has been previously assessed. THIS CAN AFFECT THE FEE

Page: 2

[h6]Check MA Memo's to find out whether or not the SUPPLIER has been previously assessed. THIS CAN AFFECT THE FEE

Page: 2

[h7]Check MA Memo's to find out whether or not the EXCIPIENTS have been previously assessed. THIS CAN AFFECT THE FEE

Page: 2

[h8]Minimum of 3 Batches with 6 Months data for NCE or 2 batches with 6 Months data for non NCE

Page: 2

Carried out under **controlled** conditions

Page: 2

[h9]Qualitative and Qualitative showing all ingrediants, quantities and grades

Page: 2

[h10] Mechanisms by which active exerts it's effect

Page: 2

[h11]Studies showing the kinetics of the active through laboratories animals/target species

Page: 2

[h12]Carried out in 2 mammalian species, or one mammalian species and the target species. 2 routes must be studied, one of which should be similar to the proposed route

Page: 2

[h13]One study carried out in one species of laboratory animal or the target species. Dosage, route of admin and duration should reflect the proposed conditions of clinical use. FOR FOOD PRODUCING ANIMALS the study must be carried out on 2 spieces one of which should be non-rodent. The oral route must be used, and the test should last for at least 90 days

Page: 2

[h14]REPROTOX (food producing) studies should be done in one rodent species using 3 doses. The max dose should show the harmful effects while the lowest dose should show no effects. The test should start prior to mating and finish at the weaning of the F2 generation.

TERATOGENICITY (food producing) should be carried out in at least 2 mammalian species (rat and rabbit).

For NON-FOOD PRODUCING the studies can be combined and should be done in at least one species.