

## Validation Form for a New Drug Master File

<b>Ingredient Name:</b>	
<b>Active Ingredient Manufacturer (AIM):</b>	
<b>TMP Number:</b>	<b>DMF Number:</b>

<b>Letter of Access?</b>
<b>Named Company (MAH):</b>
<b>Named Product(s):</b>
<b>Name and address of AIM?</b>
<b>Name and address of agent?</b>

<b>Applicant's (Open) Part:</b>	<b>Comments:</b>
Name(s) and Site(s) of AIM?	Page(s): -
Specification and routine tests?	Page(s): -
Nomenclature?	Page(s): -
Description?	Page(s): -
Manufacturing Method (brief outline)?	Page(s): -
Development Chemistry:	
- Evidence of structure?	Page(s): -
- Potential isomerism?	Page(s): -
- Physiochemical characterisation?	Page(s): -
Analytical validation?	Page(s): -
Impurities?	Page(s): -
Batch analysis?	Page(s): -
Stability?	Page(s): -
Expert Report: <i>Critique</i> ?	Page(s): -
Expert CV(s)?	Page(s): -
Summary tables?	Page(s): -

<b>Restricted (Closed) Part:</b>	<b>Comments:</b>
Name(s) and Site(s) of AIM?	Page(s): -
Previous use in medicinal products?	Page(s): -
Manufacturing Method (detailed description)?	Page(s): -
Quality Control during manufacture?	Page(s): -
Process validation?	Page(s): -
Expert Report: <i>Critique</i> ?	Page(s): -
Expert CV(s)?	Page(s): -
Summary tables?	Page(s): -