EUROPEAN COMMISSION
DIRECTORATE-GENERAL III
INDUSTRY
Industrial affairs III: Consumer goods industries
Pharmaceuticals and Cosmetics

Community Basic Format for Manufacturing Authorisation

Explanatory Notes

1. ***Purpose***
   The attached provides the basic format and content for manufacturing authorisation granted by the Competent Authorities of Community Member States in accordance with Article 16 of Council Directive 75/319/EC and Article 24 of Council Directive 81/851/EC.

2. ***Use by Competent Authorities in the EU***
   This document describes the order in which information will appear in manufacturing authorisations and the basic content of each section. Otherwise manufacturing authorisations will reflect the individual requirements of the Competent Authorities and National Legislation.

3. ***Content of the Manufacturing Authorisation***
   Manufacturing authorisations should contain, as a minimum, the information included in pages 1 - 3 in the attached model document, with the exception of sections 1 and 3 of Annex I which are optional (indicated as such in the text).
   The remaining pages consist of Annexes (2 to 7) which are optional and are to be used at the discretion of the Competent Authorities concerned.

4. ***Implementation***
   It has been agreed (at the Control of Medicinal Products and Inspections Working Party on 18/12/98) that this model format will be introduced for all new and renewed manufacturing authorisations issued by the Competent Authorities of the EU Member States from July 1st 1999 onwards.

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MANUFACTURING AUTHORISATION - COMMUNITY BASIC FORMAT

1	Authorisation Number	.....
2	Name of Manufacturer	
3	Address of manufacturing site	....
4	Legally registered address of authorisation holder	....
5	Scope of Authorisation (Manufacturing operations* / Production Activities)	See Annex 1
6	Dosage forms produced*	See Annex 1
7	Legal Basis of Authorisation *(Reference to Directives and National legislation implementing them)*	
8	Name of Responsible officer of the competent authority of the member state granting the manufacturing authorisation	.....
9	Signature	.....
10	Date	Day / month / year

Annexes attached
Annex I
Annexes 2*, 3*,4*,5*,6*, 7* (as required)

* Optional

ANNEX I

SCOPE OF AUTHORISATION:

(Please delete the areas which do not apply)

Human Medicinal Product
Veterinary Medicinal Product

1	**MANUFACTURING OPERATIONS (Categorised as per GMP Guideline) ***
1.1	Purchase of Materials
1.2	Purchase of Products
1.3	Production
1.4	Release Quality Control
1.5	Storage
1.6	Distribution
1.7	Related Controls for these operations

2	**PRODUCTION ACTIVITIES**	
2.1	**Sterile products**	
	2.1.1 Liquid dosage forms (Large Volume Parenterals)	
		- aseptically prepared
		- terminally sterilised
	2.1.2 Liquid dosage forms (Small Volume Parenterals)	
		- aseptically prepared
		- terminally sterilised
		- eye drops
	2.1.3 Semi-solid dosage forms	
	2.1.4 Solid dosage forms	- solid fill
		- freeze-dried
2.2	**Non-sterile products**	
	2.2.1 Liquid dosage forms	
	2.2.2 Semi-solid dosage forms	
	2.2.3 Solid dosage forms	
		- unit dose form (tablets, capsules, suppositories, pessaries)
		- multi dose form (powders, granules)
	2.2.4 Medical gases	
2.3	**Biological products**	
	2.3.1 Vaccines	
	2.3.2 Sera	
	2.3.3 Blood products	
	2.3.4 Other (describe: e.g. hormones, enzymes of human or animal origin, genetically engineered products)	
2.4	**Packaging only**	
	2.4.1 Liquid dosage form	
	2.4.2 Semi-solid dosage form	
	2.4.3 Solid dosage form	
	2.4.4 Medical gases	

* Optional section

3	**LIST OF PRODUCT DOSAGE FORMS ***
3.1	Oral Preparation – liquid and semi solid
3.2	Oral Preparations – solid forms
3.3	Oromucosal and gingival preparations
3.4	Preparations for dental use
3.5	Cutaneous and transdermal preparations
3.6	Eye preparations
3.7	Ear preparations
3.8	Nasal Preparations
3.9	Vaginal Preparations
3.10	Rectal Preparations
3.11	Preparations for inhalation
3.12	Parenteral preparations
3.13	Implants
3.14	Preparations for dialysis
3.15	Preparations for intravesical and urethral use
3.16	Tracheopulmonary preparations
3.17	Endocervical preparations
3.18	Intramammary preparations
3.19	Intrauterin preparations
3.20	Environmental preparations
3.21	Miscellaneous

* Optional

ANNEX 2 (Optional)

Address(es) of contract manufacturing sites	....

ANNEX 3 (Optional)

Address(es) of Contract Laboratories .....
.....
.....

ANNEX 4 (Optional)

Name of qualified person .....

ANNEX 5 (Optional)

Name of person responsible for quality control .....

Name of person responsible for production .....

ANNEX 6 (Optional)

Date of Inspection on which Manufacturing Authorisation was granted	/ / 19
Scope of last Inspection	.....

ANNEX 7 (Optional)

Products authorised to be manufactured (in accordance with Article 17 of Council Directive 75/319/EEC

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