

## CELL LINE BASED ORGAN MATERIAL BEATS BSE RISK IN ANIMAL ORGAN EXTRACTS<sup>1</sup>

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### SUMMARY

BSE-free ORGAN EXTRACTS, aqueous, protein-free, can be prepared from cell lines and/or from synthetic material: table A. Activity tests: table B (example: SWINE-Placenta-Extract).

The use of animal material for pharmaceutical and cosmetic preparations has been disrupted and restricted since the appearance of BSE (bovine spongiforme encephalopathy) i.e. since the discovery of the thermostable PRIONES (infectious Proteins). The further application of animal material in medicine and cosmetics should be only allowed if the organs are taken from animals which are living in BSE-free overseas countries. In Europe it is recommended to take fresh organs from herds in which until now *no* cases of BSE has been observed – permitting many risks and imponderabilities.

A way out is been offered by two new organ extract preparation methods, for obtaining **protein-free, BSE-free Organ Extracts**, summarized in table A under **II** und **III**. **II** is “synthetic organ extracts”, **III** is “organ extracts from BSE-free cell lines”. **I** is organ extracts from **fresh** glands.

Both new manufacturing methods for **II** resp. **III** and their applications are secured by the author’s patents in Europe and overseas countries, also protecting the combinations **III + II**, **III + I**, **III + II + I** Lit (1,2). According to **table A**, the aqueous protein-free organ extracts **III** are no longer prepared from fresh organ material – like **I** – but cell mass bred in culture starting from **definitely BSE-free** cell lines.

**II** is obtained by mixing low molecular components which are identified in natural organ extracts or which are isolated from them. The deficiency here is that certain components are lacking because not all components occurring in natural organ extracts have yet

been analyzed. This deficiency can be compensated by combining **II** and **III**. This simultaneously guarantees the economy of **III**.

Analysis of **II** and **III** to prove freedom from BSE are unnecessary.

As can be seen in **table B** optimal activity is achieved by combining organ extracts **III + II**.

### REFERENCES

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**Table A: Manufacturing Methods for Organ Extracts**

	<b>I: Normal organ extracts</b> Prepared from <u>naturally occurring</u> material (organs)	<b>II: “synthetic” organ extracts</b> prepared from “ <u>synthetic</u> ” material (chemicals)	<b>III: cell line based organ extracts</b> prepared <u>from cell lines</u> (cell banks)
Desired organ extract, protein-free, aqueous	Animal organs like kidney, thymus, blood, placenta, amnion liquid, liver, and others (slaughter houses, deep frozen material)	Low-molecular compound which are analyzed in or isolated from natural organ extracts (chemical catalogues or special preparations)	Defined cell lines of animal organs, like MDBK, P1-1A3, ATCC CL 33, RPL10, UFSM (cell banks) ecc.
Starting material for preparation of aqueous organ extract	1. Grinding (colloid mills) 2. Fat removal (organic solvents) 3. Centrifugation to obtain aqueous phase of Organ Extracts 4. Deproteinization by addition of organic acids (citric cycle acids) 5. Standardization – may be with <b>II</b> 6. Sterile filtration (0,2 um)	1. Solving in aqua bidest; the low-molecular components chosen according to the analytical results of organ extracts 2. Standardization 3. Sterile filtration (0,2 um)	1. Preparation of cell cultures to gain cell mass in sufficient quantity, later by surface or suspension culture equipment 2. Cell mass treated like <b>I</b> , 1-4 (like naturally occurring material) 3. Standardization maybe with <b>II</b> 4. Sterile filtration (0,2 um)
Preparation method (steps) according to GMP:	indispensible from outset	Possible at any time	During I, 4 (1,3)
Preserving agent	<b>I + II</b>	<b>II + III</b>	<b>III + II</b>
Combination relations	Absence of BSE not guaranteed – analytical experiments required	BSE-free, guaranteed by “synthetic” material	Guaranteed BSE-free Using BSE-free cell lines

**Table B: Activity tests of SWINE Placenta extracts prepared according to methods **III**, **III + II** and **III + I** (table A)**

Activity test	<b>III</b>	<b>III + II</b>	<b>III + I</b>
Metabolic activity (Warburg factor ) Lit. (3,4)	1,8	2,0	1,7
Growth tests			
a) Guppy fisch (length in mm after 20 days)	22,0 (18,0)*	23,2 (18,0)	21,0 (18,0)
b) Tadpole of Xenopus laevis DAUDIN, shortering of metamorphosis in days	8	10	4
Wound healing (skin tension after 21 days) values: differences between experimental and control group Lit. (2)	280	320	230
Padberg method data Lit. (2)	70 (85)*	60 (85)	70 (85)*
Humidity maintaining capacity (Corneometer)	++	+++	+

\*) in brackets: Control experiment