



DL3  
Cambrex Profarmaco Milano S.r.l.

January 2011

**TO WHOM IT MAY CONCERN**

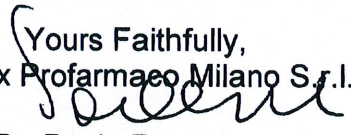
**STATEMENT**

**RE: All our products**

We, Cambrex Profarmaco Milano S.r.l., addressed in Milano (Italy) – Via Cucchiari 17, herewith confirm that for the manufacture of all our products, produced in our Plant of Paullo (Milano – Italy) – Via Curiel 34, no raw material derived from cattle, sheep, goats and cow are used.

We also confirm:

- that material is not of animal origin and it has not been produced using reagents / intermediates of animal origin;
- that our products are not derived from any raw material genetically modified.

Yours Faithfully,  
Cambrex Profarmaco Milano S.r.l.  
  
Dr. Paolo Russolo  
President



ALL

Cambrex Profarmaco Milano S.r.l.

Paullo, March 18th, 2011

Confirmation on Residual Solvents in Active Pharmaceutical Ingredient  
According to Guideline CPMP/ICH/283/95 (February 2009)

and

Current USP General Chapter < 467 >

CAMBREX PROFARMACO MILANO SRL hereby confirms for the active pharmaceutical ingredient:

**SODIUM PICOSULFATE**

evaluated according to USP <467> the following:

Class 1 solvents

We don't use class 1 solvents.

Class 2 solvents

- Chloroform
- Methylene Chloride

are likely to be present in the finished product and reported in our certificate of analysis, and they are below the class 2 limit.

Class 3 solvents

- Ethanol

is likely to be present in the finished product and reported in our certificate of analysis, and it is below the class 3 limit.

- Methanol
- Ethyl Acetate

used in the earlier manufacturing steps are not present in the finished product.

Any other solvents likely to be present

- None

- "Likely to be present" refers to solvents used in the final manufacturing step and to solvents that are used in the earlier manufacturing steps and not removed by a validated process.

This statement refers to the criteria reported in the ICH guideline for residual solvents.

Yours faithfully,

Quality Director & Qualified Person  
Dr. Domenico Casucci