



**SOLVAY
PHARMA**

Canlac
DIVISION SOLVAY PHARMA INC.



CERTIFICATE of ANALYSIS

Name of product	: Lactulose Concentrate USP / Lactulose, Liquid Ph. Eur
Lot/batch-number	: 01NF
Manufacturing date	: June 21, 2005
Retest-date	: June 21, 2006
Place and date of issue	: Victoriaville Qc, July 5, 2005
Reference	: P.F. 20 p.13-18

TEST	RESULT	REQUIREMENT	METHOD
Characters			
> appearance	complies	A clear, colourless to pale brownish-yellow viscous liquid, miscible with water	Ph.Eur.0924
Identification			
> HPLC retention time	complies	corresponds to reference standard	QCFP-002 ¹⁾
> reaction with cupri-tartaric solution ²⁾	complies	complies	USP/Ph.Eur.0924
> reaction with ammonia ²⁾	complies	complies	Ph.Eur.0924
Purity			
> clarity of a 10% m/V solution in water ²⁾	clear	clear	Ph.Eur.0924
> colour of a 10% m/V solution in water ²⁾	complies	Not more intensely coloured than reference solution BY ₅	Ph.Eur.0924
> pH of a 10% m/V solution in water	4.8	3.0 to 7.0	Ph.Eur.0924
> pH undiluted	4.8	2.5 to 6.5	USP<791>
> relative density	1.34	≤ 1.38	Ph.Eur. 2.2.5
> sulphites, in ppm	complies	≤ 30	Ph.Eur.0924
> lead, in ppm relative to lactulose ²⁾	complies	≤ 0.5	Ph.Eur.0924
> sulphated ash, in % relative to lactulose ³⁾	complies	≤ 0.2	Ph.Eur.0924
> sulphated ash, in % m/m ³⁾	complies	≤ 0.1	USP<281>
> related sugars (HPLC) in % relative to lactulose			
▪ tagatose	0.5	≤ 3	QCFP-002 ¹⁾
▪ fructose	0.0	≤ 1	
▪ galactose	12.0	≤ 15	
▪ epilactose	3.6	≤ 7	
▪ lactose	8.4	≤ 9	
▪ other related substances	6.1	≤ 8	
> refractive index at 20°C	1.462	≥ 1.451	USP<831>
> A420 (undiluted, 1 cm, 420 nm)	0.09	≤ 0.15 at release	Spectrophotometry
Content	(51.85% m/m)		
> lactulose (HPLC), in g/l	693	634 - 700	QCFP-002 ¹⁾
Microbial purity			
> total viable aerobic count or total aerobic microbial count, in 1 ml	complies	≤100 bacteria and ≤10 fungi (yeasts and moulds)	USP<61>/Ph.Eur.0924
> test on absence of E.coli in 10 ml	complies	absence	USP<61>/Ph.Eur.0924
> test on absence of Salmonella and staphylococcus, in 10 ml	complies	absence	USP<61>

Recommendation: Do not store below 0°C and preferably not above 25°C, protected from direct sunlight

Remark: The requirements regarding methanol and boron as mentioned in the Ph.Eur. monograph are not included, since methanol and boron are not used in the production process. Would comply if tested.

1) QCFP-002 is a validated method adapted from BAI-1-72-63 (Solvay Pharma method).

2) Not routinely tested: validation data yield sufficient assurance that the requirement will be met, if tested.

3) Test frequency at release: one out of five batches

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