

CERTIFICATE of ANALYSIS

Name of product	: Lactulose Concentrate USP / Lactulose, Liquid Ph. Eur
Lot/batch-number	:
Manufacturing date	: 03 January 2019
Retest-date	: 03 January 2020
Place and date of issue	: Victoriaville Qc, 25 January 2019
Reference	: P.F. 54 p. 25-32

TEST	RESULT	REQUIREMENT	METHOD
Characters			
<ul style="list-style-type: none"> > appearance 	complies	A clear, colourless to pale brownish-yellow viscous liquid, miscible with water	Ph.Eur.0924 ^C
Identification			
<ul style="list-style-type: none"> > HPLC retention time > reaction with cupn-tartaric solution 	complies complies	corresponds to reference standard complies	USP ^C USP ^C /Ph.Eur.0924 ^C
Purity			
<ul style="list-style-type: none"> > pH undiluted > relative density > sulphites, in ppm > sulphated ash, in % m/m Related sugars (HPLC) in % relative to lactulose <ul style="list-style-type: none"> ▪ tagatose ▪ fructose ▪ galactose ▪ epilactose ▪ lactose ▪ Peak No 1 ▪ Total Unknown Impurities ▪ Total impurities > refractive index at 20°C > A420 (undiluted, 1 cm, 420 nm) 	4.6 1.34 complies 0.001 0.64 <0.25 12.7 4.0 7.8 3.2 2.2 30.6 1.464 0.09	2.5 to 6.5 ≤ 1.38 ≤ 30 ≤ 0.1 ≤ 3.0 ≤ 1.0 ≤ 15.0 ≤ 7.0 ≤ 10.0 ≤ 4.0 ≤ 4.0 ≤ 37.0 ≥ 1.451 ≤ 0.15 at release	USP<791> ^C Ph.Eur. 2.2.5 ^C Ph.Eur.0924 ^C USP<281> ^C USP ^C USP<831> ^C Spectrophotometry
Content			
<ul style="list-style-type: none"> > lactulose (HPLC), in g/l 	662	634 – 700	USP ^C
Microbial purity			
<ul style="list-style-type: none"> > total viable aerobic count or total aerobic microbial count, in 1 ml ¹⁾ > test on absence of E.coli in 10 ml ¹⁾ > test on absence of Salmonella and staphylococcus, in 10 ml ¹⁾ 	complies complies complies	≤100 bacteria and ≤10 fungi (yeasts and moulds) absence absence	USP<61> ^C /Ph.Eur.0924 ^C USP<62> ^C /Ph.Eur.0924 ^C USP<62> ^C

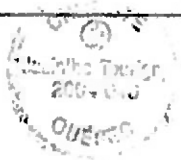
Recommendation: Do not store below 0°C and preferably not above 25°C, protected from direct sunlight

1) External laboratory testing (Neopharm lab and/or Groupe Environex)

note ^C : CURRENT VERSION

QC Supervisor

 J. Tourigny, Chemist



Support QA

 I. Domazet, PhD.