

Le Vet BV
Wilgenweg 7
3421 TV Oudewater
Nederland

Sample-code(s), 2013080344 Raamsdonksveer, 20-08-2013

Manufacturer's batch certificate

Description of the product **Benaktor F 20 mg tablets**
Pack size **Blister of 14 tablets (7 pcs)**
Product number **P3120**
Recipe/filling number **R0959 U0665**
Batch number **13 H 151**
Batch customer **13 H 151**
Manufacturing/output date **08-2013 / 08-2013**

Registration number **Zul.Nr.:401022.01.00**
Order number **PO 3521**
Batch size **997 pcs**

Method	Description Parameter	Result	Unit	Target	Lower Limit	Higher Limit	Lower warning	Higher warning
LAF005A	Average weight	396	mg	406.0	376.0	436.0	385.7	426.3
LAF005B	Uniformity of mass Measured units ≥ 18 units ≤ 2 units	20 conform conform		informative value conform conform				
	Variation	2.7	%	informative value				
LAF009A	Dimensions							
	Diameter	7	mm		6.8	7.8	6.9	7.3
	Height	5	mm		4.8	5.2		
	length	14	mm	14	13.8	14.2	13.9	
LAF010A	Shape							
	Appearance	tablet		tablet				
	Mark of division	I, double sided		I, double sided				
	Shape	oblong		oblong				
	Colour	orange		orange				
LAF011A	Disintegration time	4.08	min.			15		
LAF023A	Hardness	83	N		60	120		
LAF024A	Friability	0.1	%			1		
LAV179A	Benazepril							
	Benazepril HCl	19.7	mg/unit	20.0	19.0	21.4	19.4	21.0
	Identification Benazepril HCl	positive		positive				
LAV179B	Benazepril impurities							
	Impurity C	0.1	%			3.0		1.0
	Impurity individual	0.2	%			1.0		0.5
	Impurities total	0.6	%			2.0		1.0
LAV800A	Water according to Kroll-Fischer	1.5	%			3.0		
LAF004D	Content (pcs)	14	pcs	14				

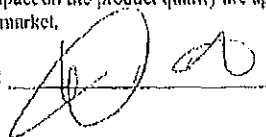
All mentioned limits are equal to or stricter than the limits mentioned in the available documentation. Additional items may be specified without actual impact on the product specifications. LAV901A = component(s) not tested; result declared on the basis of the production amounts. LAV903A = component(s) not tested; result is declared amount according to the composition.

Produlab Pharma retains samples till 1 year after the expiry date. Records of the analysis are retained for 7 years and are available on request.

We hereby certify that the above information is authentic and accurate. This batch of product has been manufactured and analysed at a qualified third party site, packaging and further quality control being performed at the below mentioned site in full compliance with the EU GMP requirements and with the specifications as agreed with the marketing authorization holder of the importing country. The batch processing, packaging, and analysis records were reviewed and found to be in compliance with GMP.

No deviations with a direct impact on the product quality are applicable for this product batch.
The batch is released into the market.

Initials qualified persons:



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Breda, acc. no. 22.56.27.076
BIC: FVLBNL22
IBAN: NL14FVL060725627826
VAT: NL8042 54 247 BQ1

Our delivery and sales conditions as deposited at the chamber of commerce under no. 18043243 apply on all deliveries and transactions.

Produlab Pharma



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Expiry date 01-2015

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Produlab Pharma bv, Forellenweg 16, NL-4941 SJ Raamsdonksveer Manufacturing licence 1401-BVEAK

P.P.A. Rompa
Laboratory manager

H.J. Nooteboom
QA manager, QP

Ob. for paper

