



# REGAL LABORATORIES

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## CERTIFICATE OF ANALYSIS OF FINISHED PRODUCT

Name of Product: PIGAZOL DSR

Generic Name: Pantoprazole & Domperidone Sustained release Capsules

Batch No.: AUC22-007

Batch Size: 5100 Capsules

Qty Sampled: 80 Capsules

Date: 08-2022

Exp. Date: 07-2024

A.R. No: FP0922549

Sampled By: Sukhbir Kaar

Mfg. By: Regal Laboratories

Supplied By: Regal Laboratories

Date of Receipt: 01-09-2022

Date of Release: 06-09-2022

PACKING PRESENTATION: 1 x 10 Capsules Packed In Alu-Alu Strip.

Tests	Specification	Result
Description	Transparent body & Orange color cap, hard gelatin capsules, having white, blue & orange color pellets.	Transparent body & Orange color cap, hard gelatin capsules, having white, blue & orange color pellets.
Identification	HPLC: The retention time of the major peaks in the chromatogram of the Assay preparation corresponds to the HPLC chromatogram of Standard preparation, as obtained in the Assay.	Complies
Average Fill Weight	302.8 mg	302.8 mg
Uniformity of weight	± 5 % w/w of average weight	Maximum: (+) 3.48 % w/w Minimum: (-) 2.69 % w/w
Dissolution	<b>Pantoprazole (Enteric coated):</b> Acid stage: Not less than 10% Buffer stage: Not less than 75 % of stated amount of Pantoprazole <b>Domperidone (Sustained Release):</b> 1 <sup>st</sup> Hour: Not less than 15% and not more than 40% 4 <sup>th</sup> hour: Not less than 30% and not more than 60% 8 <sup>th</sup> hour: Not less than 50% and not more than 85% 12 <sup>th</sup> hour: Not less than 75% and not more than 100%	Acid stage: 1.85% Buffer stage: 92.49% <b>1<sup>st</sup> Hour:</b> 23.66% <b>4<sup>th</sup> hour:</b> 48.67% <b>8<sup>th</sup> hour:</b> 69.79 % <b>12<sup>th</sup> hour:</b> 94.56%
Uniformity of Content	Not less than 85.93% and not more than 115% of label amount of Pantoprazole and Domperidone	<b>Pantoprazole:</b> Min: 97.85% Max: 103.67% Average: 101.97% <b>Domperidone</b> Min: 99.54% Max: 105.78% Average: 102.57%
Assay:		
Each hard gelatin Capsule contains: Pantoprazole Sodium IP Eq to Pantoprazole: 40 mg (As Enteric - Coated pellets)	Not less than 36 mg and Not more than 44 mg Pantoprazole Not less than 90% and Not more than 110% Pantoprazole	41.076 mg 102.69%
Domperidone IP:30 mg (As Sustained Release pellets)	Not less than 27 mg and Not more than 33 mg Domperidone Not less than 90% and Not more than 110% Domperidone	31.18 mg 103.96%

Conclusion: The Sample complies with the standards of quality as per IHS specification.

Prepared By:

Analysed By:

Approved By:

Date:

Date:

Date:

*Sukhbir Kaar*  
06-09-2022

*M*  
06-09-2022

*[Signature]*  
06-09-2022